

EXHIBIT B

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F.R.C.P. 26

PRELIMINARY REPORT OF HOWARD HU, M.D., M.P.H., Sc.D.

I am a resident of Ann Arbor, Michigan and am legally competent to provide this Affidavit. I have personal knowledge of the facts set forth herein and if called upon to testify under oath, I would testify to the matters set forth in this affidavit. In this matter, I am serving as an expert consultant. I am also the:

- NSF International Department Chair and Professor in the Department of Environmental Health Sciences at the University of Michigan School of Public Health;
- Professor of Internal Medicine at the University of Michigan School of Medicine;
- Professor of Epidemiology at the University of Michigan School of Public Health.

I received my M.D. degree from the Albert Einstein College of Medicine in New York City in 1982, a Masters of Public Health in Occupational Health from the Harvard School of Public Health in 1982, a Master of Science in Epidemiology from the Harvard School of Public Health in 1986, and a Doctorate of Science in Epidemiology from the Harvard School of Public Health in 1990. I am certified as a Diplomate by the American Board of Internal Medicine and as a Diplomate in Occupational Medicine by the American Board of Preventive Medicine. I was a tenured Professor in the Department of Environmental Health at the Harvard School of Public Health until 2006 when I moved to Michigan to become Chair of the Department of Environmental Health Sciences at the University of Michigan School of Public Health. A more complete statement of my credentials is contained in my *curriculum vitae*, a copy of which is attached as Exhibit 1.

In this brief report, I have been asked to address several issues related to the Apollo and Parks nuclear materials processing facilities: (A) the relevance of ionizing radiation to the carcinogenic potential of highly enriched uranium; (B) the current state of knowledge based on the scientific literature

regarding the impact of ionizing radiation on biological systems, the causation of cancer, and types of cancer; (C) the current state of knowledge regarding the shape of the dose-response relationship between ionizing radiation and risk of cancer at low levels of radiation; and (D) methodological issues and implications associated with the four studies conducted by Boice et al., on cancer incidence and cancer mortality surrounding the Apollo and Parks facilities (Boice et al., 2003a; Boice et al., 2003b; Boice et al., 2009a; Boice et al., 2009b).

1. The Relevance Of Ionizing Radiation To The Carcinogenic Potential Of Highly Enriched Uranium

The major exposure of concern with respect to the Apollo and Parks facilities (hereafter referred to as simply “the nuclear plants”) is the ionizing radiation emitted by enriched uranium and other radionuclides used at the facilities. I agree with the conclusion made by B&W and ARCO (Memo of Law, 2000) that when one considers the exposure as exposure to ionizing radiation, as one must, then the “scientific evidence, including epidemiological studies, [is] . . . overwhelmingly in favor of a finding that uranium exposure probably caused cancer.”

This conclusion is consistent with the epidemiological studies concerning ionizing radiation and highly enriched uranium. With respect to the nature of the risks to health associated with exposures to enriched uranium, it is clear that, as noted by the U.S. Agency for Toxic Substances and Disease Registry (2011), enriched uranium is more of a radiological hazard than a chemical hazard. As such, the risks to health associated with exposure to enriched uranium, including, primarily, the risk of cancer, derive primarily from the ionizing radiation (in the form of alpha particles) it is known to emit.

In this regard, it is critical to appreciate the distinction between uranium and enriched uranium, the latter of which can be considered a sub-type of uranium created by human industry. Enriched uranium is the product of a process that increases (or enriches) the percentages of ^{234}U and ^{235}U . Enriched uranium emits radiation energy in the form of ionizing, or alpha, radiation at a level around 7

times greater per unit mass naturally occurring uranium. Accordingly, in my opinion, highly enriched uranium can be expected to have significant carcinogenic potential on account of its radioactivity, which is several fold higher than that of natural uranium owing to its higher content of ^{235}U . In these cases, the plants were releasing highly enriched uranium that, in turn, emit ionizing radiation and thus, in my opinion, put those exposed at significant risk for contracting cancers. Furthermore, records show that the community, and thus people in the community, was exposed to several other radionuclides which also emitted ionizing radiation, in addition to the enriched uranium (such as ^{60}Co and ^{137}Cs , which emit gamma radiation; ORAU, 2009). This additional exposure also put those exposed at additional risk for contracting cancers.

I have reviewed the unpublished studies and reports of Plaintiffs' expert Bernd Franke and agree that the health effects among the residents in communities surrounding the nuclear plant emissions would have been largely dependent on levels of total exposures. Because of the regular and consistent failure of Nuclear Materials and Equipment Corporation (NUMEC) at each of its facilities to follow federal law in monitoring and documenting emissions from its facilities (*see* Report of Joseph Ring, 2011), the true levels of exposure to residents over the course of the operations of the nuclear plants will never truly be known. Based upon the little information that was recorded by the plant operators, it is clear that exposures to ionizing radiation from enriched uranium and other radionuclides among residents in the communities surrounding the nuclear plants did occur. Furthermore, based on extrapolations made by Franke & Makhijani (1998) it is my opinion that the multiple accidental releases of the ionizing radiation that are known to have occurred (but remain undocumented in terms of actual measurements of their resulting deposition in the community) were each likely to have been associated with radiation exposures to surrounding residents that greatly exceeded established dose limits.

Franke & Makhijani (1998) noted that “The occurrence of an accident involving the release of 3 kg of U-235 has been documented. Given the incompleteness of stack data, we are unable to estimate how many high release events have occurred and when,” and then went on to estimate exposures to a typical resident living in the vicinity of the nuclear plants that would have occurred from such an accidental release of 3 kg of U-235. Franke & Makhijani noted that:

The calculated doses may be compared with past or current dose limits. Up and including 1979, the lung dose limit for residents was 1.5 rem. Under the selected scenario parameters the accidental exposure in 1963 of 3 kg of insoluble U-235 would have resulted in lung doses of 9.5 to 95 rem (90% confidence interval). This dose is a factor of 6.3 to 63 larger than the permissible lung dose for 1963. In 1979, the allowable lung dose from nuclear fuel cycle operations (40CFR190) was lowered to 0.025 rem per year. The accidental dose calculated for the selected scenario is a factor of 380 to 3,800 larger than the 1979 dose limit.

Thus, in my opinion, based upon the limited data that was recorded by NUMEC and the work conducted by Franke & Makijani, the nuclear plants emitted ionizing radiation at levels that likely had significant health impacts for the residents living in surrounding communities.

This opinion is also supported by the designation of both facilities as Special Exposure Cohorts (“SEC”) pursuant to the Energy Employees Illness Compensation Program Act of 2000 (“EEOICPA”). The Apollo facility was so designated on November 29, 2007 and Parks facility was designated on May 30, 2008 (ORAU, 2009). The EEOICPA provides compensation to qualified employees who suffer from a designated cancer caused by exposure to radiation while working in the nuclear industry. Generally, the EEOICPA requires proof of radiation dose to qualify for benefits. However, employees in facilities designated as SEC facilities are entitled to compensation without having to prove individual radiation doses. The designation of the facilities as SEC indicates two things: (1) the United States government concluded that employees’ exposure to ionizing radiation from highly enriched uranium and other radionuclides was significant; and (2) that the exposures to ionizing radiation were capable of causing radiation-induced cancer.. These insights, in turn, provide support for my opinions that: (1)

members of the community could have also been exposed to highly enriched uranium and ionizing radiation from the facilities, (*See* Franke & Makhijani report); and (2) that exposure to this type of radiation is capable of causing cancers in humans.

2. The Current State Of Knowledge Based On The Scientific Literature Regarding The Impact Of Ionizing Radiation On Biological Systems, The Causation Of Cancer, And Types Of Cancer

I am familiar with the current state of knowledge based on the scientific literature regarding the impact of ionizing radiation on biological systems, the causation of cancer, and types of cancer. In my opinion, one of the most authoritative statements of relevance are the Biological Effects of Ionizing Radiation (BEIR) reports produced by the Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation of the National Research Council of the US National Academies (hereafter referred to simply as the “Committee”). In their most recent report (NRC, 2006), which focused on the health risks from exposure to low levels of ionizing radiation, the Committee concluded that “current scientific evidence is consistent with the hypothesis that there is a linear, no-threshold dose-response relationship between exposure to ionizing radiation and the development of cancer in humans”.

In terms of biology, in my opinion, radiation induces a multistage process known to result in the development of cancer that is similar to that which occurs with spontaneous cancer and cancers associated with exposure to other carcinogens. The specific process involves a dose-dependent induction of DNA damage in cells and the appearance of gene or chromosomal mutations through DNA damage misrepair. It is also now clear that cancer-prone human genetic disorders are likely to predispose individuals to an increased risk of radiation-induced cancer, probably with a high degree of organ specificity. This likely occurs through polymorphisms of DNA damage response genes, some of which are likely to be common in the general population and therefore likely to result in significant differences in susceptibility to radiation-induced cancer in the general population.

3. The Current State Of Knowledge Regarding The Shape Of The Dose-Response Relationship Between Ionizing Radiation And Risk Of Cancer At Low Levels Of Radiation

The Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation of the National Research Council of the US National Academies concluded that “current scientific evidence is consistent with the hypothesis that there is a linear, no-threshold dose-response relationship between exposure to ionizing radiation and the development of cancer in humans”. This essentially means that “the smallest dose [of radiation] has the potential to cause a small increase in risk [of cancer] to humans”. The Committee’s opinion was based on a thorough review of the epidemiological as well as experimental and radiation biology data. It is my opinion that even low levels of exposure to ionizing radiation can cause cancer in a human and that there is no threshold level for exposure to ionizing radiation. Thus, any people living near the facilities who were exposed to ionizing radiation – through a single event high dose release, multiple event high dose release, and/or through chronic exposure to ionizing radiation in the soil, air and water – are at higher risk for contracting certain cancers, including those now known to be associated with radiation exposure: leukemia, bone cancer, renal cancer, lung cancer, multiple myeloma, lymphomas, thyroid cancer, breast cancer (male and female), esophageal cancer, stomach cancer, pharynx cancer, cancer of the small intestines, pancreatic cancer, cancer of the bile ducts, gall bladder cancer, salivary cancer, bladder cancer, brain cancer, colon cancer, ovarian cancer and liver cancer.

4. Methodological Issues and Implications Associated With the Four Studies Conducted by Boice et al., on Cancer Incidence and Cancer Mortality Surrounding the Apollo and Parks Facilities

John Boice and colleagues, retained experts of the Defendants, conducted and published at Defendants’ request several epidemiologic studies related to cancer among residents living in areas surrounding the Apollo and Parks nuclear materials processing facilities in Pennsylvania (hereafter

referred to simply as “the nuclear plants”). The first two studies appeared back-to-back in a 2003 issue of the journal *Health Physics*, with one taking the form of a cancer incidence study for the years 1993-1997 utilizing data on cancer and mailing addresses obtained from the Pennsylvania Department of Health; and the other taking the form of a cancer mortality study for the years 1950-1995 utilizing data from the US Census to identify exposed v. control populations based on County of residence and data on cancer mortality from the National Center for Health Statistics. The second two studies appeared back-to-back in a 2009 issue of the same journal, *Health Physics*, and consisted of a cancer incidence study and a cancer mortality study using the same methods as those published in 2003, except that the analyses were conducted with updated data with data on cancer incidence from 1998-2004 and cancer mortality (and other causes of death) from 1996-2004.

In my opinion, the Boice et al. papers cannot be used to conclude that emissions from the nuclear plants did not contribute to the causation of cancers among residents living around the nuclear plants for the following reasons:

- a. The Boice studies are ecologic epidemiological studies which, in general, are recognized methodologically as very blunt tools for studying the relationship between environmental exposures and disease and are not necessarily powerful enough to detect patterns in small communities like the ones surrounding the Apollo and Parks Township facilities.

Specifically, the Boice studies suffer from the following methodological problems well-known to be among the limitations in ecologic epidemiological studies: (1) ecologic and cross-level bias; (2) problems of confounder control; (3) within-group misclassification (4) lack of adequate data; (5) temporal ambiguity; and (6) migration across groups.

b. Boice et al.'s assumption that levels of exposure to the emissions of the nuclear plants was simply based on living in a geographic unit and its proximity to the nuclear plants ignores:

- (i) the known wide variation in exposure from deposition that typically occurs as air emissions are dispersed over a community; and
- (ii) the non-conformity of geographic units to assumed distances from a point source of pollution (i.e., townships are not concentrically arranged around the nuclear power plants).

c. Moreover, Boice et al.'s analytic strategy and interpretation of the results suffer from other limitations related to the classification of subjects including:

- (i) the assignment by Boice et al. of the study populations into only two exposure categories ("exposed" v. "non-exposed") ;
- (ii) the non-uniform/ one sided re-assignment of individuals with cancer from the "exposed" category to the "non-exposed" category; and
- (iii) partial reliance on unsupported factual assumptions.

This 31st day of October, 2011, 2011.



Howard Hu

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